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104TH CONGRESS
2D SESSION

H. R. 3065

To amend the Federal Food, Drug, and Cosmetic Act to revise the review of radiopharmaceuticals under section 505 of such Act.

IN THE HOUSE OF REPRESENTATIVES

MARCH 12, 1996

Mr. COBURN (for himself, Mr. BURR, Mr. STUPAK, and Mrs. LINCOLN) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise the review of radiopharmaceuticals under section 505 of such Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Radiopharmaceutical Review Improvement Act of 1996''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the

Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.)

SEC. 2. REVIEW OF RADIOPHARMACEUTICALS.

(a) SEC. 505.—Section 505 (21 U.S.C. 355) is amended by adding the following new subsection at the end thereof:

''(n)(1) For purposes of this section, the safety and effectiveness of a radiopharmaceutical are to be determined—

''(A) weighing the probable benefit to health from the use of the radiopharmaceutical against any probable risk of injury or illness from such use;

''(B) taking into account the absence or presence of pharmacological and toxicological activity of the radiopharmaceutical and the estimated absorbed dose of the radiopharmaceutical.

''(2) In the case of a radiopharmaceutical intended to be used for diagnostic purposes, the indications for which such a radiopharmaceutical is approved under this section may refer to processes (such as biochemical, physiological, anatomical, or pathological), processes common to or present in one or more disease states, or may refer to a diagnostic procedure used in the diagnosis of one or more diseases.

''(3) As used in this subsection and section 503, the term 'radiopharmaceutical' means—

''(A) an article that is intended for use in vivo in the diagnosis, cure, mitigation, treatment, or prevention of disease or a manifestation of disease in men, and that exerts its primary effect by the spontaneous disintegration of unstable nuclei with the emission of ionizing radiation; or

''(B) a reagent kit or nuclide generator that is intended to be used in the preparation of any such article.''.

(b) SEC. 503.—Section 503(g)(1) (21 U.S.C. 353(g)(1)) is amended—

(1) in subparagraph (B), by striking ''or'';

(2) in subparagraph (C), by striking the period and inserting ''; or''; and

(3) by inserting after subparagraph (C) the following new subparagraph:

''(D) a radiopharmaceutical, the persons charged with premarket review of the radiopharmaceutical products shall have primary jurisdiction.''.

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